Exactech® Optetrak Logic® CRC Tibial Insert
Special 510(k) – 510(k) Summary of Safety and Effectiveness

JAN 10 2013

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 327-4762
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: Patrick Hughes
Regulatory Affairs Specialist

Date: October 29, 2012

Trade or Proprietary or Model Name(s):
Exactech® Optetrak Logic® CRC Tibial Insert

Common Name:
Cemented Total Knee Prosthesis

Classification Name:
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K111400	Optetrak Logic CR Knee System	Exactech, Inc
K121307	Optetrak Logic CR Knee System Sizes 0 and 6	Exactech, Inc

Exactech® Optetrak Logic® CRC Tibial Insert
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Indications for Use:
The OPTETRAK Comprehensive Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

In the USA, the OPTETRAK Comprehensive Knee System is indicated for cemented use only.

Device Description:
The proposed Optetrak Logic CRC Tibial Insert devices represent modifications to existing Optetrak Logic CR Knee System components cleared per 510(k) K111400 and 510(k) K121307. Both proposed and predicate devices are made from the same materials using the same processes and are compatible with the same Optetrak Logic tibial trays and femoral components. Compared to predicate Logic CR inserts, the proposed Logic CRC inserts are designed to provide additional stability in the absence of a fully functioning PCL.

The proposed and predicate devices have the same intended use and basic fundamental scientific technology and share the following similarities:

- Both made from ultra high molecular weight polyethylene per ASTM F648
- Both have the same indications for use
- Both have similar design features
- Both have the same shelf life
- Both are compatible with the same Logic devices
- Both are packaged and sterilized using the same materials and processes

Summary of Testing
Testing based on the methods detailed in ASTM F1223-08 was performed to characterize the amount of constraint introduced by the proposed dimensional changes (n=5). Compared to predicate Logic CR inserts, the results showed average Logic CRC anterior constraint increased 54%, average posterior constraint increased 14%, and average overall anterior-posterior constraint increased 34%. Average Logic CRC medial-lateral constraint increased 6% versus the predicate Logic CR devices, and average Logic CRC rotational constraint increased 33% over Logic CR. Devices were also evaluated by surgeon experts during cadaver lab testing.

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Optetrak Logic CRC Tibial Insert devices are substantially equivalent to cleared predicate Optetrak Logic cruciate-retaining tibial insert devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Exactech, Incorporated
% Mr. Patrick Hughes
Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Letter dated: January 10, 2013

Re: K123342
Trade/Device Name: Exactech® Optetrak Logic® CRC Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 10, 2012
Received: December 11, 2012

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak Logic® CRC Tibial Insert
Special 510(k) – Indications for Use

510(k) Number: K123342

Device Name: Exactech® Optetrak Logic® CRC Tibial Insert

INDICATIONS

The OPTETRAK Comprehensive Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

In the USA, the OPTETRAK Comprehensive Knee System is indicated for cemented use only.

Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

2013.01.10 13:19:20 -05'00'